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Patent Docket P1105R1D1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Blank et al.

Serial No.: 09/940,166

Filed: 27 August 2001

For: PROTEIN RECOVERY

Group Art Unit: To be assigned

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Examiner: To be assigned

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, P.O. Box 2327, Arlington, VA 22202 on

November 27, 2001

Janet TseINFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491; **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.
- ☐ **37 CFR §1.97(d)**

after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial Nos. 09/097,309 and 09/460,587, filed 12 June 1998 and 14 December 1999 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,
GENENTECH, INC.

Date: November 27, 2001

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Patent and Trademark Office

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Serial No.

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Applicant

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LIST OF DISCLOSURES OF OTHER APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- *29 Clezardin, "One-step procedure for the rapid isolation of mouse monoclonal antibodies and their antigen binding fragments by fast protein liquid chromatography on a mono Q anion-exchange column" Journal of Chromatography 319:67-77 (1985)
- *30 Duchosal et al., "Immunization of hu-FBL-SCID mice and the rescue of human monoclonal Fab fragments through combinatorial libraries" Nature 355 (6357):258-262 (Jan 16, 1992)
- *31 Gruber et al., "Efficient Tumor Cell Lysis Mediated by a Bispecific Single Chain Antibody Expressed in *Escherichia coli*" Journal of Immunology 152:5368-5374 (1994)
- *32 Holliger et al., "Diabodies": Small Bivalent and Bispecific Antibody Fragments" Proc. Natl. Acad. Sci. USA 90:6444-6448 (Jul 1993)
- *33 Jakobovits et al., "Analysis of Homozygous Mutant Chimeric Mice: Deletion of the Immunoglobulin Heavy-Chain Joining Region Blocks B-cell Development and Antibody Production" Proc. Natl. Acad. Sci. USA 90:2551-2555 (March 1993)
- *34 Jakobovits et al., "Germ-line Transmission and Expression of a Human-Derived Yeast Artificial Chromosome" Nature 362:255-258 (March 18, 1993)
- *35 Kostelny et al., "Formation of a Bispecific Antibody by the Use of Leucine Zippers" Journal of Immunology 148(5):1547-1553 (1992)
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- *37 Lindmark et al., "Binding of immunoglobulins to protein A and immunoglobulin levels in mammalian sera" J. Immunol. Meth. 62:1-13 (1983)
- *38 Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling" Bio/Technology 10:779-783 (1992)
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- *43 Morrison et al., "Chimeric Human Antibody Molecules: Mouse Antigen-binding Domains with Human Constant Region Domains" Proc. Natl. Acad. Sci. USA 81:6851-6855 (November 1984)
- *44 O'Shea et al., "Preferential heterodimer formation by isolated leucine zippers from fos and jun" Science 245(4918):646-648 (Aug 11, 1989)
- *45 Pluckthun, A., "Antibodies from *Escherichia coli*" The Pharmacology of Monoclonal Antibodies, Rosenberg and Moore, New York:Springer-Verlag, Chapter 11, Vol. 113:269-315 (1994)
- *46 Presta et al., "Humanization of an Antibody Directed Against IgE" J. Immunol. 151(5):2623-2632 (September 1, 1993)
- *47 Reif et al., "Characterization and application of strong ion-exchange membrane adsorbers as stationary phases in high-performance liquid chromatography of proteins" Journal of Chromatography A 654:29-41 (1993)
- *48 Sahni et al., "Proteosynthetic activity of immobilized *Staphylococcus aureus* V8 protease: application in the semisynthesis of molecular variants of α -globin" Analytical Biochemistry 193(2):178-185 (Mar 2, 1991)

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Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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LIST OF DISCLOSURES CITED BY APPLICANT

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

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| *49 | Shalaby et al., "Development of Humanized Bispecific Antibodies Reactive with Cytotoxic Lymphocytes and Tumor Cells Overexpressing the HER2 Protooncogene" <u>Journal of Experimental Medicine</u> 175:217-225 (Jan 1, 1992) |
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| *52 | Futt et al., "Trispecific F(ab') ₃ Derivatives That Use Cooperative Signaling Via the TCR/CD3 Complex and CD2 to Activate and Redirect Resting Cytotoxic T Cells" <u>J. Immunol.</u> 147(1):60-69 (1991) |
| *53 | Voyksner et al., "Optimization of immobilized enzyme hydrolysis combined with high-performance liquid chromatography/thermospray mass spectrometry for the determination of neuropeptides" <u>Analytical Biochemistry</u> 188(1):72-81 (Jul 1990) |
| *54 | Waterhouse et al., "Combinatorial infection and in vivo recombination: a strategy for making large phage antibody repertoires" <u>Nucleic Acids Research</u> 21:2265-2266 (1993) |
| *55 | Zapata et al., "Engineering linear F(ab') ₂ fragments for efficient production in Escherichia coli and enhanced antiproliferative activity" <u>Protein Engineering</u> 8(10):1057-1062 (1995) |

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